LIFE SCIENCES INDUSTRY OUTLOOK

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Participants in Utah Business Magazine's Tenth Industry Outlook round table discussion

On a sunny morning tinged with the feel of impending fall, experts from Utah's biomedical and biotechnology industries gathered in the downtown boardroom of Grant Thornton for Utah Business magazine's tenth Industry Outlook round table discussion.

Their conversation ranged from the current economic climate's effects on business to the continued repercussions of 9/11 to new product offerings. Obviously, these local CEOs, presidents and vice presidents are seeing their companies impacted by the volatility of the world today.

Participants included Wayne Barlow, Wescor, Inc.; David Clark, NPS Pharmaceuticals; Kelvyn Cullimore, Dynatronics Corporation; Roger Evans, Cephalon, Inc.; Steve Hamilton, Aciont, Inc.; Michael Keene, Utah State Department of Community and Economic Development; Pratap Khanwilkar, Medquest Products, Inc.; Kelly Powers, C.R. Bard Access Systems; Larry Rigby, Zars, Inc.; and Steve Sanders, Watson Laboratories, Inc.

Special thanks to Brian Moss, president of the Utah Life Sciences Association, for moderating this month's discussion.

Despite challenges to the industry, participants were enthusiastic about the scientific and medical contributions their companies have made to public health. As Moss stated, "We are able to control and prevent diseases at an unprecedented level in the history of mankind, and that is accelerating rather than decreasing."

HOW HAS OUR INDUSTRY BEEN AFFECTED BY THE EVENTS OF 9/11?

Cullimore: The core business hasn't been terribly affected. What has been affected has been the capital markets, so if you're a public company or even a private company seeking some sort of capitalization or equity or debt financing, there's definitely been a change in the market.

Barlow: Exporting your products, there's a lot more scrutiny now, particularly if they're going anywhere in the Eastern part of the world. We're having to make sure we don't do something we're not supposed to do in shipping product to an embargoed country.

Keene: There has been a sudden influx of funding for infectious disease. As you put research funding into chronic diseases such as cancer, diabetes and heart disease, at the same time is the potential for a long-term crisis with antibiotic-resistant infectious organisms. You are going to see products down the road that will have a benefit for fighting disease and treating health, but I worry

about the lack of a balanced strategy going forward, and not just sucking funding from things like cancer and other degenerative diseases solely for bioterrorism.

Barlow: So much money is being put into war efforts, there's not money available to do other things. Where the federal government was operating toward a surplus, now we've got the reverse happening. The symptom that is going to affect all of us is the active movement in Congress to revisit the issue of user fees. It's another barrier to entry, and it's going to have a negative impact on the industry.

Sanders: There's focus on internal policies and procedures and protection and travel, import/export issues with pharmaceutical products and suppliers, but the core business of supplying medications to the American public hasn't changed that much, and that business has to continue in spite of additional burden on the industry.

Rigby: The capital market has changed most dramatically. It hasn't had the effect on us yet, but we haven't been out for a round since 9/11. We're facing that with some trepidation, because the whole scenario has been altered. Not only (9/11) but because of the stock market. Those two factors create a very ugly environment for us.

THE INDUSTRY HAS DIFFICULT TIMES FINANCIALLY, BUT WE SEEM TO BE MOVING FORWARD. HOW ARE WE PROGRESSING OR FALLING BACK?

Clark: As long as you continue to make progress in the biological sense, and as the capital markets are accessible, then we continue to make progress.

Khanwilkar: We have had success in Utah, but we are also looking for external funding, and it's difficult. You're lucky if you have a patient investor who has already invested enough, otherwise (you'll) be on the street. It is difficult to take the next step in Utah. Utah has great infrastructure. It has a great mix of the university, hospitals and industry. We can communicate with each other. It's a great place to start a company, but then to take it to the next level is the hard part.

Clark: One of the challenges that we're faced with is bringing in additional talent. It's not that people are not attracted to Utah. The lifestyle and the setting is a plus, but our industry is still so small, it's tough to recruit top people here to make a commitment to a community where they know that if something does go wrong, and there is a risk in this industry, that they'll have something else to do without having to move again.

Khanwilkar: In the cardiovascular device space, people will more easily move to Minneapolis, because that's the hotbed of our industry, but if our company does not succeed, then the people who have been here don't have much of a choice and don't want to be moving. They love the community. Once people move here, they never want to go back.

Rigby: There is a core group of us in Utah now that we steal from. It's easier to get somebody here in the valley already. The indigenous development of talent is a phenomenal thing here. The University remains a gold mine in terms of early-stage talent. We found that we can bring people in and train them. We use senior consultants outside the state on an as-needed basis to mentor smart, inexperienced people. It's hard to attract senior people into a company like ours because we're 15 employees.

Barlow: Utah demands quite a bit of respect for what we do here, so although it will take time for this state to build the sort of critical mass that some of these other centers have, as we build it those things will resolve. I'm concerned about the burdens on the device industry that are emanating out of the federal government. The administration has a proposal right now to increase the fees of the U.S. Patent & Trademark Office by 50 percent. We pay to get patents processed. Our companies count on patents and on trademarks, so here is another way Congress is trying to pull money in. It will have a major impact on our companies.

Clark: We have to consider what the result might be, because a 50 percent increase in fees at the Patent Office is a small price to pay if we don't have to wait five, six, eight years to get a patent issued.

Sanders: Theratek took this jump to a new level by being acquired by Watson. It's no longer a Utah company, and there is certain attrition of people that occurred as a result. We have preserved the positions for research and development here in Utah, and there's a commitment by the company to maintain that. It's interesting to interview people coming from smaller companies that have had to downsize. They're looking for more stability. I sympathize with people's recruitment efforts. We lived that scenario, and now it's interesting being on the other side, actually getting some talented people that have come out of smaller companies, looking for more stability.

Hamilton: It seems that there's a common theme, and that is the lack of an infrastructure base of capital to be able to capitalize on innovations coming out of the universities, which falls on all of us to attract more money into the state. The current economy and conditions are probably the worst we've seen in 20 to 30 years. Part of it has to do with the national picture and part of it has to do with our ability to attract new capital into the state.

OF THE TWO ISSUES, FINANCE AND EMPLOYMENT TALENT, WHICH IS THE GREATER CHALLENGE?

Rigby: It's a vicious circle and they're both problematic, because if you have capital, you still need talent, and it's hard to lure people into a riskier venture.

Evans: It's relative to size. (At) Cephalon, financially we can pay somebody to come and be here, whereas a smaller company has more of an issue. You can't have talent come if you can't pay them.

Clark: That hasn't been our experience as a larger company; we haven't been able to attract top talent either. I have to commend the U. of U. We've had some successful intern programs. There's a lot of good engineering talent, but the big difficulty is the executive talent, and it hasn't been money that has prevented them from coming. It's a fear of this environment.

Evans: It's also the fact that if they come here, 'When is Pfizer or Merck going to come in, swallow us up, and then we'll be out of a job? We came from the East and we're going to have to go back now.' There's some trepidation.

Rigby: This is a dynamic business. There are mergers and acquisitions. Job opportunities are constantly in flux. If you look back, Salt Lake has changed dramatically. We have had institutional venture capital here. We have a university that has a technology transfer office that understands the game. We have a base of talent. We have good patent attorneys in our field. The environment changes, and you have to live by your wits. Would I advise somebody to start a company right

now? I would be reluctant to say jump into it unless it was an earth-shattering technology with good patents and a huge market need. If it were a little niche, I would say wait until the environment changes.

Hamilton: It may be an issue of threshold. We are smaller, and we need to grow to that threshold to attract incremental capital, and the people will come in. It's not like the Delaware Valley, where if it doesn't work out, there are 50 companies to choose from, and you don't even have to change your car pool.

IS IT NEGATIVE OR POSITIVE THAT WE HAVE LARGER COMPANIES COMING IN TO ACQUIRE OUR UTAH COMPANIES?

Cullimore: It's positive because the natural business cycle requires that. To take it to the next level, you have to be able to access those opportunities, attracting capital, attracting personnel, talent--the more critical mass you have, the better off we are as an industry.

Clark: NPS acquired a Canadian company. We have Toronto facilities now, and we will undoubtedly have other facilities in other areas and that will help with our recruiting process. Mergers and acquisitions, that's an important and positive element in what we're trying to accomplish.

barlow: I worry about what we're doing to the small entrepreneurial companies. Not the people (who) have got the new innovation that are going to change medicine, but the guy (who's) developing something that will make laboratory operations safer or something that might protect against needle sticks or some other small thing. You don't see those companies anymore. There are too many barriers to entry, and that's worrisome in terms of the long-term effect on the quality of healthcare in the U.S.

IS THE PIPELINE REALLY DRYING UP?

Barlow: In the period from 1983 to1993, there was a decrease in the number of companies serving the diagnostic laboratory market of about 41 percent. We saw hundreds of companies die because they couldn't get a product on the market. The startups you see today in the device field are those that have got an idea powerful enough to attract $10 or $15 million of venture capital. The bootstrap company that runs the credit cards to the max, mortgages the house, borrows from Aunt Matilda - you don't see those. It'll take several generations for that to have an impact on public health, but it'll have a negative impact. The fact that the U.S. is no longer the unchallenged world leader in medical technology is evidence of what we've lost.

Moss: The reimbursement--government and the HMOs, the large group-purchasing organizations (GPOs)--set formularies for what they will reimburse for a particular diagnostic procedure. Our industry is dependent upon what will be reimbursed for a particular therapy or disease symptom. The industry may come up with the greatest product in the world, that doesn't mean that the government will reimburse through Medicare or Medicaid. It doesn't mean that HMOs are going to reimburse. If we don't get on that list for reimbursement, then our product may save lives, but it's never going to be in the marketplace.

Rigby: Goods are marketed differently than they were 10 years ago. The formularies and the POs have power over what is purchased and what even pricing is. Little companies will not have the power to move their products themselves. They have to establish alliances with larger companies that are looking for innovative products.

Cullimore: There's a distinction between the pharmaceutical-related companies and the medical device companies, and yet they are sometimes used by the community as one biotech group. While there are definite similarities, the medical device side is different. We do have success in trying to market devices through a proprietary distribution network. There are not the giants in our industry like there are dominating the pharmaceutical side.

Barlow: The device industry is small. In 1994, of all the companies listed with the FDA, 98 percent of them were small businesses by the government's definition. Sixty-four percent had fewer than 20 employees.

Khanwilkar: There is very little middle left. There's a huge number of small companies doing the R&D for these large companies, and they can change the projects that come to fruition. The pipeline is going to dry up because their products, which are useful, which can be cost-effective, are not going to see the light of day in the market. There are a lot of small companies in the medical device industry, but if you look at the revenues that are generated, there are 10 or 15 device companies that are generating 90 percent of the revenue in the device market.

HAVE FINANCIAL MARKETS BECOME MORE EDUCATED TO OUR INDUSTRY?

Rigby: The alliance does bring capital. If you're a royalty-based company, how do you condition yourself for investors? Getting the alliances, if you have good technology and talent, is fairly easy to do, and they bring capital, support, distribution.

Evans: Big companies don't have time to keep coming up with the pipeline. We develop the pipeline for them. These wonderful ideas that come out of the state are going to be beneficial because (with the) good products that we develop here, then those companies either do collaborations or come in and pick up the company.

Powers: I wanted to resonate the advantage that the larger company has with the GPOs. A small company doesn't have a complete catalog to compete and balance and put one product against another. At the same time, with the conservatism that goes with the bigger company, we lose our ability to innovate, so we draw that from smaller companies. We have a lot of alliances. We commercialize and sell, and we draw from the rest of you who have those ideas.

WHAT CAN WE BE DOING AS AN INDUSTRY TO KEEP THE SMALL ENTREPRENEUR MOVING FORWARD, TO ALLOW THEM TO SEE SOME OPPORTUNITY?

Keene: We're focused on that link between where the Centers of Excellence program, for example, lets off--where you've gotten something that now is matured from science to technology to perhaps a prototype, but not yet to the point where it's ready to be an up-and-going company or a part of the product portfolio of Bard or Cephalon. It needs more incubation. You've got a sloppy interface. At what point are you incubating technology, and at what point are you incubating a company? We are looking at several models and mechanisms of funding and structuring to come up with a new level of incubation for advanced technology and emergent companies here.

Powers: I've been trying to get close to the tech transfer office. There isn't a good communication channel with the larger companies. They're interested in those seedling technologies and in a position to fund studies. It's difficult to extract what's going on in (the) tech transfer office and learn about it. It's not that it's proprietary or secret. It's just that they haven't ever done that, and one of the biggest disadvantages with a lot of these seedling technologies is complete disconnection with the market need and the way things are distributed, and sometimes those are the killer for business.

Khanwilkar: At some point there (needs to be) a fund or some assistance set up to have companies grow and do that ourselves. Traditionally, the IAF has shied away from putting money into "high-risk companies." Once they are past the prototype stage and the feasibility is proven, (they can) establish manufacturing in Utah and grow jobs and all that good stuff that makes economic sense. It does carry some risk, because it would be with smaller companies that have a higher risk of going under at some time.

Moss: The Association has supported (the contingent tax credit), which basically is providing a government-guaranteed return for investments going into high technology, including medical device and biologic products in Utah. The contingent tax credit provides a backing to the banks, who then lend the money to an organization that is basically a venture capital group. We are getting back to that proposition again in an effort to try to get the smaller companies some access to capital. Just a comment about the legislative process: Everyone is concerned about the high cost of medical treatment and medicines, and (their) answer to that is slap a price control on that. That means maybe they'll have access to this year's breakthrough product, but there's not going to be next year's breakthrough product if we start putting price controls on this industry that constrain our ability to innovate. We as an industry have made enormous contributions to public health. We are able to control and prevent diseases at an unprecedented level, but those technologies come at an expense. So the efforts in Congress right now to try to put controls on our industry we resist heavily. We are at risk of being legislated back into an earlier era of less good medicine, because we aren't willing to pay the cost of tomorrow.

WHAT'S COMING HERE IN UTAH? I'D LIKE TO TALK ABOUT THINGS THAT YOU'RE AWARE OF THAT ARE COMING THAT PROVIDE SOME HOPE FOR IMPROVEMENTS IN MEDICINE.

Evans: The product (Actiq®) that we manufacture currently is being used in Europe, and we've filed an sNDA with the FDA to manufacture Actiq for the U.S. That would give us worldwide manufacturing here for Actiq, currently indicated for breakthrough cancer pain. In Cephalon's pipeline, there's a lot of work in degenerative diseases and cancer, whether it be Alzheimer's, Parkinson's or solid tumors in cancer patients. In Utah, we continue to do research in transmucosal drug delivery and look forward to the worldwide manufacturing of Actiq.

Sanders: Our biggest product is for maintenance of blood volume in patients undergoing hemodialysis. We're hoping to launch a new product for overactive bladder. We have an innovative delivery system for an old drug, oxybutynin, but we've put that in a transdermal system. Many of the products we're developing are in the quality-of-life arena. We've got another product for toenail fungus. We're working on transdermal systems as well as oral controlled release and immediate release products for cancer pain.

Rigby: We take existing drugs and figure out innovative ways to get them into the body. Our focus has been the pain market. Our products that are in phase III are for numbing the skin before painful procedures. One is a cream that you put, for example, over your face, and in 30 minutes it sets up into a rubberized mask that you strip off and your face is densely numb. We are also working on cancer pain with opiates. We are working on a series of pain products for joints, muscles and myofascial pain. We have a heating patch that is integrated on top of the drug patch, and it brings the temperature of the skin up perhaps 10 degrees Centigrade higher. You can facilitate the flux through the skin dramatically.

Powers: We're primarily in the business of vascular access for cancer and are market leaders in the areas of implanted ports, chronic catheters and PICCs. We have a clinical assessment program where we assess patients earlier in their treatment process so they get the right vascular access device. We are also in the area of hemodialysis access catheters where the biggest challenge is the formation of thrombus and subsequent infections on catheter surfaces. As a result, our innovations are in the area of preserving the life of the device with antimicrobial or antithrombus coatings. Another business we have is in portable ultrasound guidance for vascular access. This allows clinicians to make needle punctures in nonvisible veins. A new platform product for us is in the area of chronic pain management with intrathecal catheters and delivery pumps.

Khanwilkar: Medquest is developing technologies for end-stage congestive heart failure and cardiovascular diseases. Over five million people in the U.S. have congestive heart failures, so it's a huge problem and it's going to get worse with the aging population. This is a breakthrough technology that we have: It's called an LVAD, a left ventricular assist device. We don't replace the natural heart, but we supplement it, so it's like a booster pump. The neat thing is the spinning part does not touch; it uses magnetic gravitation. There is no friction, no wear, which has been the Achilles' heel of this technology. They are a couple of years away from starting to sell these (as an) alternative to heart transplant.

Clark: NPS and Astrozenica have formed a joint venture to explore receptors in the body called metabotropic glutamate receptors, which are modulatory receptors of the common neurotransmitter glutamate. They are located throughout the central nervous system and in other tissues. We think they have application in a variety of diseases that range from pain to schizophrenia to epilepsy to anxiety. We've discovered these receptors in gastrointestinal tissues, and we've had some success in animal models of diseases including gastroesophageal reflux disease.

Hamilton: Aciont, Inc. uses proprietary technology to non-invasively deliver drugs to treat diseases of the back of the eye. Age-related macular degeneration and diabetic retinopathy are the number one and number two causes of blindness in the U.S. Inflammatory conditions such as posterior uveitis accounts for an additional 10 percent. Current treatments for inflammation include injections into or around the eye and surgical implants into the eye. Aciont's approach will use currently available medicines to treat inflammatory diseases without invading the integrity of the eye. New medicines under development will be used in this system to stop the progression of the main causes of blindness.

Cullimore: One of (Dynatronics') most exciting (products) is the low-power laser device. We've been battling the FDA for 20 years and finally (have approval for it) to be used for accelerating wound healing and pain management. That's a new field that has been around for a long time but just recently opened up. We will be introducing a line of electrotherapy and ultrasound products for the physical medicine market, and we have a pain management device. We are doing research up

at the U. of U. with their pain management center. Hopefully, that study will open doors. It's pain management through electrical stimulation.

Barlow: Wescor is the leader in the laboratory diagnosis of cystic fibrosis. We introduced a product in 1983 called Macroduct. The procedure is called the sweat test. You collect a sample of sweat from the child and then analyze it for its electrolyte content. Children that have CF express more salt in their sweat. Macroduct has become the methodology of choice for diagnosing this disease. The only limitation is that the Macroduct is about the size of a wristwatch. You can use it on a newborn that's seven or eight pounds and adequately get a sweat sample, but for smaller babies, it's just physically too large. Medical training has underscored the importance of early diagnosis. Although the disease is not yet curable, it can be successfully mitigated through proper treatment. This year, we introduced our Nanoduct System, which is designed to work on the smallest neonate. Now we can do this diagnosis in the first days, if not the first hours of life, and a physician can then get the child treatment.

Keene: We stand at the cusp of a new era in medicine, of gene-based diagnosis and therapy that will alter the way medicine is managed in generations to come. We're not only going to be able to know from day one whether a child is going to develop CF; we're going to know whether you are one of the five percent that is going to react badly to therapy 'A' without having to find out the hard way. Utah is strategically positioned to play a leading role in this new era because of the resources that we have in terms of clinical information, genetics, the infrastructure here. With proper encouragement and nourishment, we could end up being a major, important center for this general thrust of development for the next couple of decades. UB